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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,851	10/04/2001	Khatijah Mohd Yusoff	S1436/7007 (JRV)	1596

7590 10/15/2004

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,851	YUSOFF ET AL.	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *3-6,8,10,12 and 14-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,9,11 and 13* is/are rejected.

7)☒ Claim(s) *11 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1, 2, 7, 9, 11 and 13 in the reply filed on August 20, 2004 is acknowledged. Claims 3-6, 8, 10, 12 and 14-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Specification

2. The specification is objected to for minor informalities:

- The use of the trademark "pTrcHis2 TOPO®" (page 17, line 3, for example) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.
- The company name, "Invitrogen" is misspelled on page 17, line 3 of the specification.

Information Disclosure Statement

3. The listing of references in the specification on pages 19-20 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore,

unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The benefit of the filing date of foreign application PI 2000 4837, filed October 16, 2000 in Malaysia (in English), is acknowledged, and a copy of the application has been placed in the filed. The Declaration for Patent Application filed January 9, 2002, incorrectly states that the foreign application was filed October 4, 2001. However, the application data sheet, also submitted on January 9, 2002, correctly states that the foreign application was filed October 16, 2000. According to 37 CFR 1.76(d)(2), for inconsistencies between information that is supplied by both an application data sheet under this section and by an oath or declaration under §§ 1.63 and 1.67, the information in the application data sheet will govern when the inconsistent information is supplied at the same time by a § 1.63 or § 1.67 oath or declaration, except as provided by paragraph (d)(3) of this section (relating to the naming of inventors and the setting forth of their citizenship).

Claim Objections

5. Claims 11 and 13 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). In the interests of compact prosecution, the Office will examine claims 11 and 13 to the extent that they can be interpreted, despite their improper form.

6. Claims 11 and 13 are further objected to because of the following informalities:

- Claim 11 recites, "[A] transformed *Escherichia coli* with the recombinant expression plasmid according to claim 7 or claim 9." It is apparent from the specification that the *E. coli* is transformed with the plasmid of claim 7 or 9, resulting in the claimed transformed *E. coli*. However, the awkward claim language could be misinterpreted to be an already-transformed *E. coli* that is transformed again with the additional plasmid of claims 7 or 9. Appropriate correction is required.
- Claim 13 recites, "[T]he transformed microorganism according to claim 11", which refers to the transformed *E. coli* of claim 11. Claim 13 also recites, "the transformed *E. coli* TOP10", which refers to an *E. coli* that has been transformed with plasmid. Since there is no literal support for the terms "the transformed microorganism" or "the transformed *E. coli* TOP10" in claim 11, Applicant is advised to amend the claim language in order to avoid any indications of a lack of antecedent basis in claim 11.
- In claim 13, the recitation of the plasmid in parentheses in the phrase, "*E. coli* TOP10 (pTrcHis2-NP)", is apparently being used to refer to the plasmid of claim 9, as opposed to the plasmid of claim 7. The use of parentheses should be avoided in order to prevent any misunderstanding of the relationship between the *E. coli* TOP10 and the plasmid. Suggested sample language is, "The *E. coli* of claim 11, wherein the recombinant expression plasmid is pTrcHis2-NP, and the *E. coli* is *E. coli* TOP10."

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 is drawn to a nucleic acid molecule encoding the full-length or part of the nucleocapsid (NP) protein of Newcastle disease virus (NDV). The claim reads on a naturally-occurring nucleic acid sequence encoding an entire NDV, which is a product of nature. Claim 2 is drawn to a nucleic acid molecule encoding the full-length NP protein of NDV, *comprising* SEQ ID NO: 1. By using "comprising", claim 2 encompasses a nucleic acid molecule that is the entire viral genome of NDV. According to the specification, SEQ ID NO: 1 was determined by Applicant from strain AF2240 of NDV (specification, page 1, lines 17-21). Lacking any evidence to the contrary, AF2240 appears to be a natural NDV strain. Therefore, SEQ ID NO: 1, though previously unknown prior to Applicant's work, is an inherent property of the AF2240 strain. Whether or not anyone knew the sequence of the nucleocapsid gene of AF2240, the genome of this particular strain existed and naturally contained the sequence represented by SEQ ID NO: 1. Since claim 2 encompasses the entire viral genome of AF2240, claim 2 reads on a product of nature. Suggested preamble language to overcome this rejection is, "[A]n isolated nucleic acid molecule", or "[A] purified nucleic acid molecule".

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It is apparent that plasmid *pTrcHis2-NP* is required to practice the claimed invention because it is a necessary limitation for the success of the invention as stated in claims 9, 11 and 13. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of *pTrcHis2-NP*. See 37 CFR 1.802. The specification only discloses that the NP gene is cloned into pTrcHis2 and then introduced into *E. coli* TOP10 cells (page 13, lines 23-30). (Note that *E. coli* TOP10 cells and *pTrcHis2* (disclosed on page 17, lines 6-7 and page 13, lines 24, respectively) are known and commercially available products. *E. coli* TOP10 cells can be purchased from Invitrogen®, as catalog numbers C4040-10, C4040-03, and C4040-06, for example. Plasmid *pTrcHis2* can also be purchased from Invitrogen®, as catalog numbers K4410-01, K4400-01 and K4400-40. (See online catalog print-outs for each of the above products.)) The specification does not provide a repeatable method for making the exact same plasmid as Applicant's *pTrcHis2-NP* and it does not appear to be readily available material.

Deposit of *pTrcHis2-NP* in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating

that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7, 9, 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 and dependent claims 7, 9, 11 and 13 are drawn to a nucleic acid molecule encoding the full-length NP protein of NDV, comprising SEQ ID NO: 1. Claim 2 and dependent claims 7, 9, 11 and 13 are also drawn to a nucleic acid molecule encoding just a part of the NP protein of NDV, wherein the nucleic acid molecule comprises SEQ ID NO: 1. It is unclear how SEQ ID NO: 1 encodes for the full-length NP protein, and at the same time, is capable of encoding *just* a part of the NP protein. The specification and the claims fail to provide a clear explanation. Clarification and correction are required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Peeters *et al.* (*Journal of Virology*, June 1999, 73(6):5001-5009, herein, "Peeters"). Claim 1 is drawn to a nucleic acid molecule encoding the full-length or part of the nucleocapsid (NP) protein of Newcastle Disease virus (NDV). Broadly interpreted, claim 1 encompasses a complete viral

genome. Claim 7 is drawn to a recombinant expression plasmid containing the NDV nucleocapsid gene of claim 1. Peeters discloses a full-length cDNA clone of NDV vaccine strain LaSota that is cloned into a plasmid (abstract). Also disclosed are DNA fragments containing the NP, P and L genes of the LaSota strain, cloned into expression vector *pCIneo* (page 5002, second column, first full paragraph). Therefore, the claims are anticipated by Peeters.

The Office notes that the asserted novelty of the invention is the determination of the nucleotide sequence of the NP gene (SEQ ID NO: 1) of the NDV strain AF2240. However, claims 1 and 7, as written, broadly encompass any strain of NDV. Should Applicant amend the claims to include the strain AF2240, there may be a deposit requirement for the strain in compliance with the Budapest Treaty.

11. Claims 1, 7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Errington *et al.* (*Journal of General Virology*, 1997, 78:2335-2339, herein, "Errington"). Claims 1 and 7 have been summarized above. Claim 11, an improper multiple dependent claim, has been interpreted as best as possible to be an *E. coli* cell transformed with the recombinant expression plasmid of claim 7. Errington discloses the cloning of the NDV NP gene into the *E. coli* expression vector *pRSETB* (Invitrogen®), see page 2336, first column, first full paragraph). Therefore, the claims are anticipated by Errington.

Conclusion

12. No claim is allowed. Claims 1, 2, 7, 9, 11 and 13 are rejected. Claims 11 and 13 are objected to. SEQ ID NO: 1 is free of the prior art of record.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
October 14, 2004